

Jill Castellano <jillcastellano@inewsource.org>

RE: Forward: Journalist writing about inaccurate information in your research papers

3 messages

yizhi_liu <yizhi liu@aliyun.com>

Wed, Jul 17, 2019 at 3:12 AM

Reply-To: yizhi liu <yizhi liu@aliyun.com> To: jillcastellano <jillcastellano@inewsource.org> Cc: "kang.zhang" <kang.zhang@gmail.com>

Dear Ms. Castellano,

Dr Kang Zhang forwarded your email to us. We are glad to hear from you again. We have corresponded and addressed your questions previously regarding our clinical trial directed to us. Here is our response to your inquiries below.

Twenty-six ophthalmologists from around the world have written to Nature since your study published, raising serious concerns about the research. Some of them spoke with me for this story. They have described the study as unethical, misleading and dangerous, and they said the study would never have approved by IRB in the U.S. or been performed here.

Our Response: Thank you for your interest in our study. Actually, many respected researchers and ophthalmologists worldwide have shown great interest and made helpful comments on our study after the initial publication. Among them, some concerns and misunderstanding also existed at the early stage. However, after detailed communication and discussions in several international conferences, our study has been wellunderstood now. The BRIEF COMMUNICATIONS published in Nature has demonstrated this process and our reply to all the concerns raised by the two research groups (including the three concerns you have mentioned in this email). The clinical study was approved by our IRB and carried out in China according to accepted international standards. All the children received this minimally invasive surgery have a very good prognosis. The clinical team in China are currently conducting a longer-term follow up study to gain additional data about long-term safety and efficacy. We are happy to share that the postoperative 5-year outcomes demonstrate very good prognosis in the follow-up cohort.

Here are a few of their many concerns about the study:

• The surgeries were tested on infants in both of their eyes, rather than just one eye. That means if the experiment went wrong, the researchers could have blinded the babies.

Our Response: Basically, the new minimally invasive surgery is not "new" but more "minimally invasive" than the traditional one, with the notion of a smaller opening, less injury/trauma and less interference of the intraocular environment, as well as reducing additional drug treatment or operations. Based on this consideration, both eyes received the same minimally invasive surgery can decrease the risk of potential surgery related inflammation complications, ocular and possibly neural complications. The outcomes have also shown our "First do no harm" consideration and have afforded the infant eye a better chance for improved ocular development and good bilateral visual outcome.

- The surgery was tested on infants in the same study it was tested on animals, rather than attempting animal studies first. Our Response: The surgery was tested repeatedly on a large number of animals, including rabbits and monkeys for a long time before our clinical observation.
- The paper said 100% of the children regrew clear, functional lenses. But the study's photos and data show the babies actually had worse vision than what one would expect from existing treatments. In fact, all of the babies were still legally blind after surgery.

Our Response: As we have responded in the BRIEF COMMUNICATIONS, the children in our study had normal visual outcomes accordingly at different age stages. Our clinical team are also conducting a longer-term follow up study to gain additional data about long-term safety and efficacy. They are happy to share that the postoperative 5-year outcomes demonstrate very good prognosis in the follow-up cohort.

Thank you for your interest in our study and we welcome you to come visit our eye center.

Sincerely,

Yizhi Liu, MD PhD

Professor and Director Zhongshan Ophthalmic Center Sun Yatsen University

On Jul 17, 2019, at 13:51, Yizhi Liu <yzliu62@yahoo.com> wrote:

Hi Dr. Zhang,

I am reaching out to you again to follow up on my previous email. I am soon going to be publishing a story about your research study on lens regeneration in infants with congenital cataracts.

Twenty-six ophthalmologists from around the world have written to Nature since your study published, raising serious concerns about the research. Some of them spoke with me for this story. They have described the study as unethical, misleading and dangerous, and they said the study would never have approved by IRB in the U.S. or been performed here. Here are a few of their many concerns about the study:

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- The surgery was tested on infants in the same study it was tested on animals, rather than attempting animal studies first.
- The paper said 100% of the children regrew clear, functional lenses. But the study's photos and data show the babies actually had worse vision than what one would expect from existing treatments. In fact, all of the babies were still legally blind after surgery. If you have time, I'd really like to speak with you for this story so I can include your perspective. You can reach me at 1-914-629-1750.

I have until noon Wednesday (tomorrow) Pacific Time to finish this up. Thanks very much.

Sincerely, Jill Castellano

以下是转发的邮件:

发件人: Kang Zhang <kang.zhang@gmail.com>

日期: 2019年7月17日 GMT+8 08:26:06 收件人: Yizhi Liu <yzliu62@yahoo.com>

主题: 转发: Journalist writing about inaccurate information in your research papers

Prof Liu,

Pls see below. Let me call you to discuss.

Pls feel free to call me anytime.

Thanks, Kang

Begin forwarded message:

From: Jill Castellano <i illcastellano@inewsource.org>

Date: July 17, 2019 at 00:22:44 GMT+8

To: kang.zhang@gmail.com

Subject: Re: Journalist writing about inaccurate information in your research papers

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Sincerely, Jill Castellano

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Jill Castellano Investigative Data Reporter, *inewsource*

Email: jillcastellano@inewsource.org

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n inewsource.org

yizhi_liu <yizhi_liu@aliyun.com>
Reply-To: yizhi_liu <yizhi_liu@aliyun.com>

To: jillcastellano <jillcastellano@inewsource.org> Co: "kang.zhang" <kang.zhang@gmail.com>

To further address your comment on doing surgeries on both eyes, the decision was made only after a smaller group of patients underwent the procedure to establish acceptable safety and efficacy, before proceeding to a full study.

学体 A:vizhi liu zvizhi liu@alivun com>

发件人: yizhi_liu <yizhi_liu@aliyun.com> 发送时间: 2019年7月17日(星期三) 18:12

收件人: jillcastellano@inewsource.org>

抄 送: kang.zhang@gmail.com>

主 题: RE: Forward: Journalist writing about inaccurate information in your research papers

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Wed, Jul 17, 2019 at 9:28 AM

To: yizhi_liu <yizhi_liu@aliyun.com>

Cc: "kang.zhang" <kang.zhang@gmail.com>

Thank you very much, Dr. Liu. I appreciate your thorough replies and hope I have not bothered you with my questions. I of course want to make sure everything I write is accurate.

Sincerely, Jill Castellano

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